

Sandt & Associates
900 Deerfield Court
Midland, MI 48640
(E-mail: billsandt@chartermi.net)

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| Re: | SN 10/019570 | | |

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Message

Applicant: Jin Po Lee
Serial No: 10/019,570
Filed: 11/8/2001
For: Multiple Analyte Assay Device
Group Art Unit: 1743 Examiner: Lyle A. Alexander

Attached please find a response to the Office Action dated 11-26-2004 together with a revised list of claims, a power of attorney, a terminal disclaimer and my check for the terminal disclaimer fee. Please direct all further correspondence to the undersigned attorney


Bernd W. Sandt

IN THE UNITED STATES PATENT & TRADEMARK OFFICE**Applicant: Jin Po Lee****Serial No: 10/019,570****Filed: 11/8/2001****For: Multiple Analyte Assay Device****Group Art Unit: 1743****Examiner: L. A. Alexander****RECEIVED
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**Mail Stop Amendment
Commissioner for Patents
P.O Box 1'450
Alexandria, VA 2231'3-1450**

RESPONSE B**Sir:**

**In response to the Office Action dated 11/26/20004 please amend
claims 1, 8, and 17 as set forth in the attached listing of claims.**

Claims 9, 20, 22, and 24 are withdrawn.

**In response to the double patenting rejection applicant submits that the claims
of the present invention read on a single test strip in each slot whereas the claims of
commonly owned US Patent No. 6,514,769 call for multiple test strips in each slot.
Furthermore the integrity strip does not contain a control zone or line as called for in
the test strips in the claims of this application. Clearly there is therefore no double
patenting. However in order to advance the prosecution to allowance applicant has
filed a terminal disclaimer as suggested by the examiner.**

**Applicant has amended claim 1 to correct a typographical error (see for
example claim 10) and has corrected claims 8 and 17 to avoid the rejection under 35
USC 112. Thus as is shown in applicant's drawings and in the specification as well as**

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in claim 10 it is always the upstream end of the strip that is protruding and that contacts the sample solution. The sample flows by capillary action from the exposed and protruding upstream end through the test strip past the test and control sites to the downstream end, which is covered by the device. Clearly the use of the term downstream in the claim with respect to the protruding ends is a typographical error and entry of the amendment is respectfully requested.

Claims 1-20, 22 and 24 have been rejected under 35 USC 102 (b) as being anticipated by Kimrov et al, US patent No. 5,770,458 (hereafter Kimrov).

Kimrov relates to an assay in which the assay strips are totally encased in the assay housing and in which all strips contained in the essay housing are fed the analyte solution to be analyzed by a single pad stretching across all assay strips. Thus Kimrov fails to disclose or suggest the concept of a protruding test strip that can be immersed in to a sample solution. Furthermore even though the assay strips appear to be maintained in the housing without contacting each other, it is not clear that if excess sample exudes from a test strip in the housing, cross contamination of the adjacent assay strips is prevented. Such contamination could have a radical effect on the reliability of the test results. It appears that in order to actually supply samples to the assay strips in Kimrov, pressure has to be applied to the sample pad by means of squeezing a flexible rubber cover in order to get the assay sample to flow into the assay strip.

In applicant's assay device on the other hand each assay strip protrudes out of the housing and maintains its integrity not only in the housing but also above the housing. By having the assay strips protrude out of the housing will acquire its own sample for analysis by directly absorbing a sample amount from the sample through capillary action. Similarly within the housing each strip is maintained in its separate compartment to prevent cross contamination of the analyses being conducted. In

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applicant's assay strip furthermore capillary action is the sole means necessary to transport the sample through the strip to obtain the test results. No additional pressure is necessary as is the case in Kimrov. Furthermore such additional pressure could cause the sample to exude from the strip and cause cross contamination

It is clear that the advantage of applicant's device is the ease with which it can be used while still providing integrity to the assay results. Thus the sample does not have to be placed in a special vessel before the analysis can be performed. In applicant's device all that needs to be done is for the protruding ends of the device to be dipped into the sample for a time sufficient for the strips to absorb sufficient of the analyte solution to conduct the assay.

It is believed well-established law that in order to anticipate the reference must show every element of the claimed invention (see decisions cited in MPEP 2131). Kimrov fails to disclose or suggest the protruding assay strips of applicant's claims and fails to suggest the integrity of the analysis in each assay strip by failing to disclose or suggest separate compartments for each assay strip. Applicant's claims are deemed to be patentable over Kimrov.

Claims 1-9, 18 and 22 have been rejected under 35 USC 102(b) as anticipated by Chipowski US Patent No. 5,976,895 (Chipowski).

Chipowski discloses an assay device in which an assay card is dipped into a cup containing the assay sample to be analyzed. The assay card has permanently mounted on it a multiplicity of assay strips. The assay strips are either exposed to the atmosphere without a cover or they are laminated to the base and the cover without freedom of movement.

The examiner has rejected applicant's claims on the basis of the projections (25) protruding from closure 15 shown in Figure 1 of Chipowski. However the projections in that drawing are the downstream end of the test card and the sample actually flows in a direction reverse to that in which applicant's sample flows. Thus

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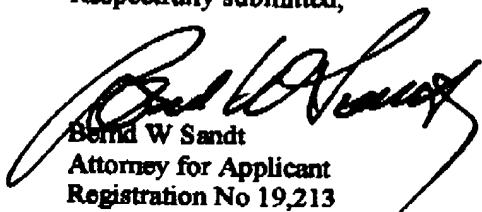
in applicant's device the sample flows from the protruding ends of the strips whereas in the drawing the sample flows to the protruding end.

Chipowski furthermore fails to teach the isolation of each test strip so as prevent any communication between the strips. Although Chipowski in one embodiment provides slots for the test strips as shown in Figure 3 and 7, the slots are not deep enough to prevent the strips from protruding above the base as shown in Figures 5 and 6. Thus even if a cover is applied to the strips there still is a possibility of contamination between the strips since they are in open communication with each other. In applicant's invention the slots have walls that are raised sufficiently to be in contact with the cover and thus isolate each test strip in the slot. Maintaining the integrity of the test strip and thus thereby the test results is an important feature of the device claimed by applicant. No such protection is provided by the test devices shown in Chipowski.

Again as pointed out above in order to find anticipation every element of the claimed invention must be found in the cited art. The reference fails to suggest the element of individual slots in the housing, which totally protect the test strips from contamination by having walls that extend to the cover.

The claims 1-9, 18 and 22 are therefore deemed to be patentable over Chipowski.

Respectfully submitted,



Bernd W Sandt
Attorney for Applicant
Registration No 19,213
900 Deerfield Court,
Midland, MI 48640
Tel: (989) 631-6852
Fax: (989) 835 6030

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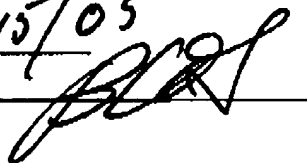
Certificate under 37 CFR 1.8

I hereby certify that a copy of the foregoing Response has been forwarded to Group Art Unit 1743 to the attention of examiner L. A. Alexander by facsimile on the date set forth below.

Date:

2/15/05

Signature



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